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June 1999

Dockets Management Branch (HFA-305)
FDA rm 1061
5630 Fishers Lane,
Rockville, MD 20852

Subject: Comments on Proposed Amendment

Ref: Docket No. 93N-0044

This letter is to express concern regarding the proposed classification change from IIIa to 3b as would apply to many construction/alignment lasers with visible outputs in the 1.5 mW range -

A significant portion of our business would be adversely impacted by this proposal. Products that have been sold as Class IIIa for many years would be re-classified as Class 3b under the proposed regulations. As the proposal is currently drafted, these products could not be sold for construction/surveying/alignment applications due to the limitations in 1040.11b. The alternative to re-design products to accommodate the proposed Class 3a limits is not realistic, due to engineering costs but primarily due to the fact that the less visible beam at the required lower power level would not be as useful to customers.

Even if that restriction is lifted to allow low power Class 3b to be used for such applications, there would be conflicts with user laser safety standards. The ANSI 136.1 standard, state regulations, and industrial laser safety standards typically rely on the CDRH classification scheme, and they place many more restrictions and apply more control measures (including appointment of a Laser Safety Officer) on Class 3b than on Class 3a installations. Thus purchasers would be subjected to a level of user regulation for Class 3b that would be expensive and inconvenient with no real increase to public safety. This would result in a significant negative impact on sales of our products.

Thus we recommend that the proposal be revised to allow products which are currently Class IIIa to remain within the proposed class 3a classification. An alternative would be to wait for the proposed amendments to the IEC 825-1 standard to be adopted that would accommodate these power levels with a new classification.

It should also be noted that as the proposal is drafted, current Class IIIa products would be adversely impacted by the proposed human access definition in 1040.10 b(14) and by the proposed interlock requirements in f(2)(iii)(A). There is little public safety to be gained by increased requirements on these low power products that have been safely used by thousands of customers for many years.

93N-0044

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1. Spectra Precision agrees with the change to eliminate requirements for an emission indicator and beam attenuator for systems in class 3b having visible output power 5mW or less.
2. Eliminate the requirement 1040.10 (f) (g) (ii) scanning safeguard failures. Use of labels that are warning labels (CAUTION) that comply with IEC 6025.
3. Surveying lasers-beams are not viewed but are captured electronically and therefore the current standard regulation promotes safe use with adequate safety margins. Any reduction in output power will render the technology useless.
4. After reviewing numerous possible situations and the affect for the changes to the IEC and the CDRH laser safety requirements Spectra Precision would like to remain as a proponent of the CDRH proposed amendment to the 21 CFR 1040 laser performance standard as published in the Federal Register Wednesday, March 24 1999 purposed rules.

If you need any clarification on these comments, please contact the undersigned.

Regards,

Robert H. Taylor
Laser Safety Officer

cc: Jerome Dennis (HFZ-312)
CDRH Office of Compliance
2098 Gaither Rd.
Rockville, MD 20850

Raj Shaida
Bill Norvell

sao



5475 Kellenburger Road, Dayton, Ohio 45424-1099

Dockets Management Branch (HFA-305)
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5630 Fishers Lane
Rockville, MD 20852

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2 Your Internal Billing Reference Information

3 To

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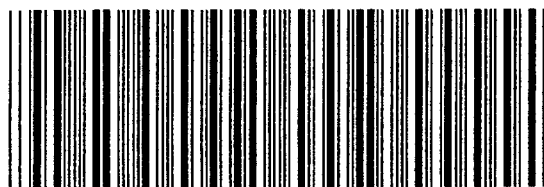
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